

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference KW0099 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/JP 03/4602 | International filing date (day/month/year) 11.04.2003 | Priority date (day/month/year) 12.04.2002 |
| International Patent Classification (IPC) or national classification and IPC Int.Cl. A61K31/4545, 31/4468, A61P35/00, C07D401/14, 401/06, 405/14, 401/12 | | |
| Applicant KOWA CO., LTD. | | |

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| <ol style="list-style-type: none"> 1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet. <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p> |
| <ol style="list-style-type: none"> 3. This report contains indications relating to the following items: <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application |

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|---|--|----------------|
| Date of submission of the demand 16.09.2003 | Date of completion of this report 26.01.2004 | |
| Name and mailing address of the IPEA/JP Japan Patent Office 3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan | Authorized officer KOJI ITO | 4C 3229 |
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I. Basis of the report

1. With regard to the elements of the international application:*

 the international application as originally filed the description:pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____ the claims:Nos. _____, as originally filed
Nos. _____, as amended (together with any statement) under Article 19
Nos. _____, filed with the demand
Nos. _____, filed with the letter of _____ the drawings:sheets/figs _____, as originally filed
sheets/figs _____, filed with the demand
sheets/figs _____, filed with the letter of _____ the sequence listing part of the description:pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in written form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. The amendments have resulted in the cancellation of: the description, pages _____ the claims, Nos. _____ the drawings, sheets/figs _____5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,
 claims Nos. 46-60

because:

the said international application, or the said claims Nos. 46-60
relate to the following subject matter which does not require an international preliminary examination (specify):

The subject matters of claims 46-60 relate to a method for treatment of the human body by therapy.

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):

the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for said claims Nos. 46-60

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

the written form has not been furnished or does not comply with the standard.
 the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|-------------|-----|
| Novelty (N) | Claims | <u>1-45</u> | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | <u>1-45</u> | YES |
| | Claims | | NO |
| Industrial applicability (IA) | Claims | <u>1-45</u> | YES |
| | Claims | | NO |

2. Citations and explanations (Rule 70.7)

D1=[EP 0774257 A2]

1. Claims 1-30

The subject matters of claims 1-30, that is to say, "a histone deacetylase inhibitor, a medicine for treating cancer, and a gene therapy facilitator comprising a cyclic amine compound represented by the formula(1)", are neither disclosed in the closest prior document D1 cited in the ISR nor obvious to a person skilled in the art.

Therefore, the subject matters of claims 1-30 appear to be novel and to involve an inventive step.

2. Claims 31-45

The subject matters of claims 31-45, that is to say, "the use of the cyclic amine compound represented by the formula(1) for producing histone deacetylase inhibitor, medicine for treating cancer, and gene therapy facilitator", are neither disclosed in the closest prior document D1 cited in the ISR nor obvious to a person skilled in the art.

Therefore, the subject matters of claims 1-30 appear to be novel and to involve an inventive step.